K042516

NOV - 8 2004

Summary of Safety and Effectiveness

Device Name: OtoMimix™

Classification Name and Reference:

Product Code: NEA

Device Classification: Class II

Device Description: OtoMimix™ is a sterile calcium phosphate Bone Replacement product. When mixed with a sterile setting solution, it becomes moldable material for use in otology procedures. With time, this moldable filler material hardens.

Intended Use: OtoMimix™ is indicated for use in the following: 1. Augmentation or coupling of the middle ear ossicles. 2. Attachment of the middle ear ossicles to middle ear implants. 3. Mechanical stabilization of middle ear prostheses. 4. Reconstruction of the posterior canal wall.

Materials **Powder component – calcium phosphate powder and sodium citrate dihydrate**
Liquid component – anhydrous citric acid and distilled water

POSSIBLE ADVERSE EFFECTS

1. Wound complications including hemotoma, site drainage, bone fracture, infection, and other complications that are possible with any surgery. Any of these complications can lead to failure of the procedure and further surgery.
2. Fracture or extrusion of the filler, with or without generation of particulate debris.
3. Deformity of the bone at the surgical site.
4. Incomplete or lack of osseous ingrowth into bone void, as is possible with any bone void filler.
5. Implantation of foreign materials can result in an inflammatory response or allergic reaction, or subsequent cholestotoma.

Substantial Equivalence

The OtoMimix™ product is believed to be substantially equivalent in application and function to

Mimix (Craniofacial Calcium Phosphate Ceramic Bone Void Filler (K990290)
Oto-Cem® – OtoTech®, Inc. (K011338)
Incus Stapes Prosthesis – Richards Medical, Inc. (K861369)

Walter Lorenz Surgical, Inc. is a wholly owned subsidiary of Biomet, Inc. The proposed OtoMimix™ product is equivalent in material characteristics and processing methods to the approved Mimix. Only packaging will change, slightly, to accommodate a smaller volume of material (0.5 to 5 grams). The anticipated size to be delivered to the market is 2 grams.

The approved HA middle ear prostheses (Richards, Xomed) are composed of the same material class (hydroxyapatite) and have the same field of use (middle ear applications).

The approved Oto-Cem device and the proposed OtoMimix device have an equivalent application in the cementing of ossicles of the middle ear.

Based on the characteristics of these predicate devices, the safety and effectiveness of OtoMimix is assessed to be substantially equivalent to approved devices for the same intended use in restoration of hearing by restoring the function of the ossicular chain.

Summary of Substantial Equivalence

	Proposed OtoMimix	Approved Oto-Cem	Approved Mimix Biomet, Inc. K 990290, K003494	Approved Incus Stapes Prosthesis - Richards Medical Co., Inc. K861369 Subsequent HA middle ear prostheses (e.g. Xomed)
Material	Calcium Phosphate cement Same as Mimix Predicate	Hybrid glass polymer composite	Calcium Phosphate cement	No 510K summary available. 1st approved hydroxyapatite prosthesis known to be marketed by Richards in 1986 Hydroxyapatite
Indications for use	1. Augmentation or coupling of the middle ear ossicles. 2. Attachment of the middle ear ossicles to middle ear implants. 3. Mechanical stabilization of middle ear prostheses 4. Reconstruction of the posterior canal wall	"for use in otological surgery for reconstruction of the ossicular chain"	"...neurosurgical burr holes, craniotomy cuts and other cranial defects as well as in the augmentation or restoration of bony contour in the craniofacial skeleton."	No 510K summary available.

Contraindications	1. Applications requiring placement directly on the footplate of the stapes 2. Existing acute or chronic infections, especially at the site of the operation. 3. Stress bearing applications. 4. Surrounding material is non-viable or is incapable of supporting or anchoring the implant.	"... must not be placed 1) in direct contact with cerebral and nerve tissue, with cerebral spinal fluids and inner ear fluid ... 2) directly on the dura mater, 3) for treatment of soft tissue and cartilage defects, 4) in cases in which a postoperative radiotherapy of the implantation site or the adjacent area cannot be excluded, 5) with known hypersensitive reactions against one or more components of polymaleinate ionomer, 6) in cases of severe systemic diseases, especially with renal insufficiencies."	1. Existing acute or chronic infections, especially at the site of the operation. 2. Stress bearing applications. 3. Surrounding bone is non-viable or is incapable of supporting or anchoring the implant.	No 510K summary available.
Ototoxicity	Demonstrated to be non-ototoxic (Dornhoffer *et al.)*	No information available	Demonstrated to be non-ototoxic (Dornhoffer *et al.)*	No information available – commonly used for middle ear prostheses
Use	Single Use	Single Use	Single Use	Single Use
Sterility	Provided Sterile	Provided Sterile	Provided Sterile	Provided Sterile
Technological Features	• 2 component cement • Hand Mixed • HA material • History of clinical use near dura, CSF	• 2 component cement • Mixing Machine • Polymaleinate derived cement • Contraindicated for use near nerve tissue	• 2 component cement • Hand Mixed • HA material • History of clinical use near dura, CSF	• Preformed Implant • No mixing required • HA material • Extensive history of middle ear use

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 8 2004

Walter Lorenz Surgical, Inc.
c/o Ms. Kim Reed
1520 Tradeport Dr.
Jacksonville, FL 32218

Re: K042516
Trade/Device Name: OtoMimix™
Regulation Number: 21 CFR 872.3275
Regulation Name: Ear Nose and Throat (ENT) Cement
Regulatory Class: II
Product Code: NEA
Dated: September 15, 2004
Received: September 16, 2004

Dear Ms. Reed:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number K042516

Device Name: OtoMimix™

Indications for Use:

OtoMimix™ is indicated for the following:

1. Augmentation or coupling of the middle ear ossicles.
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3. Mechanical stabilization of middle ear prostheses
4. Reconstruction of the posterior canal wall

Prescription Use XX AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K042516

(Posted November 13, 2003)